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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,232	03/28/2001	Motoharu Seiki	1241.18	7030

7590 08/12/2005

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EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,232	SEIKI, MOTOHARU	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S-0-D

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, and 23 (as dependent from claims 1 and 2), drawn to a metalloproteinase with the amino acid sequence of SEQ ID NO: 1 or an amino acid sequence differing by one or several amino acids therefrom by deletion, substitution or insertion.

Group II, claim(s) 3, 4, and 23 (as dependent from claims 3 and 4), drawn to a metalloproteinase with the amino acid sequence of SEQ ID NO: 2 or an amino acid sequence differing by one or several amino acids therefrom by deletion, substitution or insertion.

Group III, claim(s) 5, 6, and 24 (as dependent from claims 5 and 6), drawn to a metalloproteinase with the amino acid sequence of SEQ ID NO: 5 or an amino acid sequence differing by one or several amino acids therefrom by deletion, substitution or insertion.

Group IV, claim(s) 7, 8, and 24 (as dependent from claims 7 and 8), drawn to a metalloproteinase with the amino acid sequence of SEQ ID NO: 6 or an amino acid sequence differing by one or several amino acids therefrom by deletion, substitution or insertion.

Group V, claim(s) 9, 11, 13-16, and 25, as they depend from claims 1 and 2, drawn to a DNA encoding the metalloproteinase of group I.

Group VI, claim(s) 9, 11, 13-16, and 25, as they depend from claims 3 and 4, drawn to a DNA encoding the metalloproteinase of group II.

Group VII, claim(s) 10, 12-16, and 26, as they depend from claims 5 and 6, drawn to a DNA encoding the metalloproteinase of group III.

Group VIII, claim(s) 10, 12-16, and 26, as they depend from claims 7 and 8, drawn to a DNA encoding the metalloproteinase of group IV.

Group IX, claim(s) 17, as it depends from claims 1 and 2, drawn to a method of recombinant production of the polypeptide of group I.

Group X, claim(s) 17, as it depends from claims 3 and 4, drawn to a method of recombinant production of the polypeptide of group II.

Group XI, claim(s) 17, as it depends from claims 5 and 6, drawn to a method of recombinant production of the polypeptide of group III.

Group XII, claim(s) 17, as it depends from claims 7 and 8, drawn to a method of recombinant production of the polypeptide of group IV.

Group XIII, claim(s) 18 and 27, as they depend from claims 1 and 2, drawn to an oligonucleotide identical to 5-60 consecutive nucleotides of a nucleotide sequence encoding the metalloproteinase of group I.

Group XIV, claim(s) 18 and 27, as they depend from claims 3 and 4, drawn to an oligonucleotide identical to 5-60 consecutive nucleotides of a nucleotide sequence encoding the metalloproteinase of group II.

Group XV, claim(s) 19 and 28, as they depend from claims 5 and 6, drawn to an oligonucleotide identical to 5-60 consecutive nucleotides of a nucleotide sequence encoding the metalloproteinase of group III.

Group XVI, claim(s) 19 and 28, as they depend from claims 7 and 8, drawn to an oligonucleotide identical to 5-60 consecutive nucleotides of a nucleotide sequence encoding the metalloproteinase of group I Group XV, claim(s) 19 and 28, as they depend from claims 5 and 6, drawn to an oligonucleotide identical to 5-60 consecutive nucleotides of a nucleotide sequence encoding the metalloproteinase of group IV.

Group XVII, claim(s) 21, 31, and 32, as they depend from claims 1 and 2, drawn to a method for detecting an mRNA encoding the metalloproteinase of group I.

Group XVIII, claim(s) 21, 31, and 32, as they depend from claims 3 and 4, drawn to a method for detecting an mRNA encoding the metalloproteinase of group II.

Group XIX, claim(s) 21, 31, and 32, as they depend from claims 5 and 6, drawn to a method for detecting an mRNA encoding the metalloproteinase of group III.

Group XX, claim(s) 21, 31, and 32, as they depend from claims 7 and 8, drawn to a method for detecting an mRNA encoding the metalloproteinase of group IV.

Group XXI, claim(s) 22, as it depends from claims 1 and 2, drawn to a method for inhibiting expression of a metalloproteinase of group I.

Group XXII, claim(s) 22, as it depends from claims 3 and 4, drawn to a method for inhibiting expression of a metalloproteinase of group II.

Group XXIII, claim(s) 22, as it depends from claims 5 and 6, drawn to a method for inhibiting expression of a metalloproteinase of group III.

Group XXIV, claim(s) 22, as it depends from claims 7 and 8, drawn to a method for inhibiting expression of a metalloproteinase of group IV.

Group XXV, claim(s) 29, as it depends from claim 1 and 2, drawn to a vector for gene therapy comprising an oligonucleotide of group XIII.

Group XXVI, claim(s) 29, as it depends from claim 3 and 4, drawn to a vector for gene therapy comprising an oligonucleotide of group XIV.

Group XXVII, claim(s) 30, as it depends from claim 5 and 6, drawn to a vector for gene therapy comprising an oligonucleotide of group XV.

Group XXVIII, claim(s) 30, as it depends from claim 7 and 8, drawn to a vector for gene therapy comprising an oligonucleotide of group XVI.

The inventions listed as Groups I-XXVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

37 CFR 1.475(b) states:

> An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
>
> (1) A product and a process specially adapted for the manufacture of said product; or
>
> (2) A product and process of use of said product; or
>
> (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
>
> (4) A process and an apparatus or means specifically designed for carrying out the said process; or
>
> (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

> If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

37 CFR 1.475(d) also states:

> If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).

37 CFR 1.475(e) further states:

> The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim.

In view of 37 CFR 1.475 (b)-(e), Group I is considered the main invention to the product first mentioned in the claims.

Groups I, V, IX, XIII, XVII, XXI, and XXV; groups II, VI, X, XIV, XVIII, XXII, and XXVI; groups III, VII, XI, XV, XIX, XXIII, and XXVII; and groups IV, VIII, XII, XVI, XIX, XXIII, and XXVII are directed to inventions relating to a metalloproteinase identical or similar in sequence to SEQ ID NOs: 1, 2, 5, and 6, respectively. Each of these metalloproteinases are structurally and, in some cases, functionally different from each other. Their special technical features, if any, reside in the amino acid sequences or nucleotide sequences of each metalloproteinase. As indicated above, claims directed to different products, as here, do not have unity of invention.

Furthermore, metalloproteinases, polynucleotides encoding them, and recombinant production of them were known in the prior art, including the metalloproteinases identical or similar to SEQ ID NOs: 1, 2, and 6, see for example Kajita et al. and Llano et al. provided on the Information Disclosure statements of 3/28/01 and 7/23/01. These products do not define a special

technical feature, and thus there is no special technical feature linking the products to methods of making them or of using them. As for the inventions relating to oligonucleotides of 5-60 nucleotides in common with the polynucleotides encoding the various metalloproteinases, Brennan, US 5,474,796, discloses an array comprising all possible 10-mer oligonucleotides. Thus, the claimed oligonucleotides do not define a special technical feature, and there is no unity of invention between the oligonucleotides and methods of using them, as in groups XVII-XXIV or combinations comprising them as a subcombination, as in groups V-VIII and XXV-XXVIII. Furthermore, as indicated inventions directed to different methods of using a product are not recognized as having unity of invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott D. Priebe

Scott D. Priebe, Ph.D.
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Art Unit 1633